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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,345	09/05/2003	Pamela L. Plouhar	265280-73406	7805

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BARNES & THORNBURG  
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INDIANAPOLIS, IN 46204

EXAMINER
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STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/656,345

Applicant(s)

PLOUHAR ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11, 12, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 13 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/18/04; 02/17/04; 02/12/04; 09/05/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Species V in the reply filed on 03/08/05 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 08, 2005.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 11, 12 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7 and 9 of U.S. Patent No. 6,638,312 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both cases disclose a bioprosthetic device comprising a sheet of

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naturally occurring extracellular matrix and a sheet of synthetic mesh coupled to the naturally occurring matrix.

Claims 1-5, 7, 8, 11, 12, 14 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6 and 31 of copending Application No. 2002/0038151. Although the conflicting claims are not identical, they are not patentably distinct from each other because both cases disclose a bioprosthetic device comprising a sheet of naturally occurring extracellular matrix and a sheet of synthetic mesh coupled to the naturally occurring matrix.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Vacanti et al US Patent 6,027,744.

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Vacanti et al discloses a prosthetic device comprising an extracellular matrix portion (14) having a solidify hydrogen composition (16) with live cells (18) and a synthetic mesh portion (12) coupled to the extracellular portion (see col. 11, lines 1-20). The synthetic material and the extracellular matrix portion are biodegradable (see col. 5, lines 21-24; and col. 7, lines 10-11). Additionally, the synthetic fiber is made of Vycryl (see col. 6, lines 1-4). Regarding the extracellular matrix, the claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). For the above reasons, the Examiner has used only a prosthetic device having tissue precursor cells.

Claims 1-5 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Buirge et al US Patent 5,693,085.

Buirge et al discloses a bioprosthetic device comprising asheet of naturally occurring extracellular matrix and a sheet of synthetic mesh coupled to the matrix. The matrix is a sheet of SIS and the device is a top tissue layer of naturally occurring extracellular matrix and is coupled to a bottom tissue layer of naturally occurring matrix and the sheet of synthetic mesh is coupled to and positioned between the two layers (see Fig. 7; col. 4, lines 6-24; and col. 5, lines 10-15).

***Allowable Subject Matter***

Claims 9, 10, 13 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alvin J Stewart  
Primary Examiner  
Art Unit 3738

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**

April 01, 2005.